

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

IN RE: NEW ENGLAND COMPOUNDING
PHARMACY, INC. PRODUCTS LIABILITY
LITIGATION

MDL No. 2419
Master Dkt. 1:13-md-02419-RWZ

THIS DOCUMENT RELATES TO:

Musselwhite v. Unifirst Corporation, et al.
Docket No. 13-cv-13228; and
Kennedy, et al. v. Unifirst Corporation, et al.
Docket No. 1:13-cv-13227

**PLAINTIFFS' STEERING COMMITTEE'S MEMORANDUM OF LAW IN
OPPOSITION TO APAC DEFENDANTS' CONSOLIDATED MOTION TO DISMISS
PURSUANT TO FED. R. CIV. P. 12(b)(2) AND 12(b)(6)**

INTRODUCTION

It is undisputed that the widespread outbreak of fungal meningitis, which gave rise to this multi-district litigation, was caused by contaminated preservative free methylprednisolone acetate (“MPA”) compounded by New England Compounding Center, Inc. (“NECC”) being administered to patients at over 70 pain clinics, orthopedic practices and hospitals,¹ including the APAC Defendants.² Liability extends to the health care providers and facilities that purchased the contaminated products and distributed them to their patients. Despite extensive guidelines setting forth doctors’ and clinics’ responsibilities when outsourcing risky compounded drugs, the APAC Defendants failed to perform any due diligence. Instead, the APAC Defendants mail ordered hundreds of vials of prescription preservative free MPA from NECC without any reasonable effort to assess and evaluate NECC’s ability to aseptically make, package and dispense preservative free MPA.

The Master Complaint³, filed by the Plaintiffs’ Steering Committee on November 5, 2013 and incorporated by reference through the filing of the Short Form Complaints in the above-captioned related actions by the responding Plaintiffs, sets forth in great detail the reasons why these healthcare providers, including the APAC Defendants, share responsibility for Plaintiffs’ injuries and harm. Without APAC’s negligent and reckless conduct in mail ordering and purchasing contaminated steroids and administering them to patients without performing any due diligence the Plaintiffs would not have received contaminated MPA in their spinal column

¹ See CDC, Multistate Fungal Meningitis Outbreak Investigation, <http://www.cdc.gov/hai/outbreaks/meningitis-map-large.html> (Visited March 2014); see also FDA, Multistate outbreak of fungal meningitis and other infections, <http://www.fda.gov/%20Drugs/DrugSafety/FungalMeningitis/default.htm>; Smith, Rachel M., et al., *Fungal Infections Associated with Contaminated Methylprednisolone Injections*, N Engl J Med 2013; 369:1598-1609 (Oct. 24, 2013).

² “APAC Defendants,” “Defendants,” and/or “APAC” refers collectively to Defendants Advanced Pain & Anesthesia Consultants, P.C. d/b/a APAC Centers for Pain Management and Randolph Y. Chang, M.D.

³ Master Complaint against UniFirst and Clinic-Related Defendants, Dkt. No. 545, as amended by Dkt. No. 832, hereinafter “Master Complaint” or “Complaint.”

causing them to suffer serious injuries. The factual and legal allegations in the Master Complaint concerning the “Clinic Related Defendants”⁴ are thorough, well-pleaded, and sufficiently state claims upon which relief can be granted. Plaintiffs plead an actionable multi-count case that the APAC Defendants without due, proper and necessary qualification of NECC’s competence and ability acquired and administered adulterated preservative free MPA from NECC, and, importantly, did so by submitting prescriptions to NECC that violated Massachusetts’ controlled substances law⁵, Massachusetts’ consumer protection law⁶, Illinois Products Liability Law⁷, and Illinois’ Consumer Protection Laws⁸.

The Master Complaint is lengthy and describes in a detailed manner how the APAC Defendants’ conduct contributed to the outbreak. For example, the Complaint alleges that Defendants failed to exercise reasonable care to ensure that the drugs they purchased and administered to Plaintiffs were manufactured in compliance with applicable pharmaceutical laws. Master Compl., ¶ 234(a). The Complaint alleges that the APAC Defendants failed to perform the necessary diligence to determine the safety and quality of NECC’s drugs and failed to determine if NECC could properly provide sterile, preservative free drugs for administration to patients. Master Compl., ¶ 234(d). The Complaint also sets forth how the APAC Defendants failed to conduct sufficient due diligence to determine whether NECC was a reputable and safe supplier of sterile injectable compounds and the Complaint asserts that APAC purchased compounded drugs in bulk from NECC without using patient specific individual prescriptions as

⁴ The Master Complaint lists a number of facilities that received recalled lots of MPA from NECC. Those hospitals, clinics, healthcare facilities, and their physicians, staff, agents, and employees are referred to in the Master Complaint collectively as the “Clinic Related Defendants.” Master Compl. ¶¶ 22-23. The APAC Defendants are included in this defined term. *Id.* at 22. In addition, because the Master Complaint was adopted and incorporated by reference in each of the above-captioned related actions, the term “Clinic Related Defendants” has come to include and apply to the APAC Defendants.

⁵ MGL Ch. 94C §1 et seq.

⁶ MGL Ch. 93A.

⁷ Illinois Products Liability Law.

⁸ Illinois Consumer Fraud and Deceptive Business Practices Act.

required by law. Master Compl., ¶ 234(j)(q). In addition, the Master Complaint avers that as a result of APAC's conduct, Plaintiffs were administered contaminated products causing serious injuries and, in some cases, death. Master Compl., ¶¶ 270, 271, 298, 303, 355.

The Master Complaint and the Short Form Complaints (by adoption and incorporation by reference) set forth the following causes of action against the APAC Defendants: Count III – Negligence and Gross Negligence; Count IV – Violation of the Illinois Consumer Protection Statute (Ill. Comp. Stat. Ann. ch. 815, 505/1 et seq.); Count VIII – Failure to Warn; Count IX – Illinois Product Liability Claims; Count X – Agency; Count XI – Civil Conspiracy; Count XIII – Loss of Consortium; and Count XIV – Punitive Damages. Each Count is sufficiently pled, establishing a plausible entitlement to relief, especially where the allegations are to be construed in the light most favorable to Plaintiffs.⁹

The APAC Defendants filed the instant Rule 12(b)(2) and 12(b)(6) Motion to Dismiss. However, for the reasons below, Plaintiffs have more than adequately stated their claims and APAC Defendants' Motion to Dismiss should be denied in its entirety.

STANDARD OF REVIEW

In deciding a motion to dismiss, “a court does not rule on the evidentiary sufficiency of a complaint, only on whether its factual and legal assertions allege ‘a plausible entitlement to relief.’” *Balerna v. Gilberti*, CIV.A. 09-10075-RGS, 2010 WL 4878286, at *4 (D. Mass. Nov. 24, 2010); (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 559 (2007)). In considering a motion to dismiss, the court should “treat as true all well-pleaded facts, viewing those facts in the light most favorable to the plaintiff, and drawing all reasonable inferences therefrom for

⁹ Plaintiffs concede that dismissal of Count VII, alleging battery, is warranted in light of Illinois case law. Therefore, Plaintiffs withdraw their Count VII claim for Battery.

[plaintiff].” *Knowlton v. Shaw*, 704 F.3d 1, 3 (1st Cir. 2013) (*citing Gagliardi v. Sullivan*, 513 F.3d 301, 305 (1st Cir. 2008)). Under *Twombly*, a complaint need only allege “enough factual matter (taken as true) to suggest” the validity of the claim. *Twombly*, 550 U.S. at 557. “To justify a dismissal on any Civ. R. 12(b)(6) motion, the court must find beyond doubt from the complaint that the plaintiffs can prove no set of facts entitling them to relief.” *Saylor v. Providence Hosp.*, 113 Ohio App. 3d 1, 3-4, 680 N.E.2d 193, 194-95 (1996).

When evaluating a Civ. R. 12(b)(2) motion, the court “applies a *prima facie* standard and construes the facts affirmatively alleged by [plaintiff] ‘in the light most congenial to [their] jurisdictional claim.’”

LAW AND ARGUMENT

I. This Court has Personal Jurisdiction Over The APAC Defendants

Plaintiffs’ properly served their complaints on the APAC Defendants, establishing personal jurisdiction over them pursuant to F.R.C.P. Rule 4(k)(1)(A). Notably, the APAC Defendants cannot deny that they were properly served with Plaintiffs’ complaints. *See Exhibit A.* Instead, the APAC Defendants base their entire argument that this Court has no personal jurisdiction over them on a misunderstanding of the applicable law. Indeed, the APAC Defendants focus their argument on subject matter jurisdiction premised on diversity alone. However, the Master Complaint alleges subject matter jurisdiction related to a federal question in that, “[t]his Court has subject matter jurisdiction over the parties pursuant to 28 U.S.C. § 1334(b) because, as described herein, each claim asserted is related to a case under title 11, because the outcome of the proceeding could have some effect on the bankruptcy estate.” *See Master Compl., ¶ 11.* Because the APAC Defendants misplace their argument on diversity jurisdiction, it is wholly inapposite and their motion under F.R.C.P. Rule 12(b)(2), therefore, meritless.

Where a federal district court’s subject matter jurisdiction is based, not on diversity of citizenship (as claimed by the APAC Defendants), but on the existence of a federal question arising out of a federal statute, the “personal jurisdiction inquiry … differs from the inquiry in diversity cases.” *United States v. Swiss Am. Bank, Ltd.*, 274 F.3d 610, 618 (1st Cir. 2001). To begin, a federal court’s jurisdiction “is grounded in, and limited by, statute.” *Celotex Corp. v. Edwards*, 514 U.S. 300, 307 (1995). Where a proceeding is in federal court on “related to” jurisdiction under § 1334(b), as these cases are, the “entire body of Bankruptcy Rules … applies to [the] action.” *In re Celotex Corp.*, 124 F.3d 619, 629 (4th Cir. 1997); *see also Diamond Mortg. Corp. of Ill. v. Sugar*, 913 F.2d 1233, 1242 (7th Cir. 1990) (“Bankruptcy Rule 7004(d) applies to all ‘adversary proceedings’ (as defined by the Bankruptcy Rules) conducted in the bankruptcy courts or in the district courts.”).

Bankruptcy Rules 7004(d) permits service of process to be effected “anywhere in the United States”; subsection (f) provides further as follows:

If the exercise of jurisdiction is consistent with the Constitution and laws of the United States, serving a summons or filing a waiver of service in accordance with this rule or the subdivisions of Rule 4 Fed.R.Civ.P. made applicable by these rules is effective *to establish personal jurisdiction* over the person of any defendant with respect to any case under the Code or a civil proceeding arising under the Code, or arising in or related to a case under the Code.

Fed. R. Bankr. P. 7004(f)(*emphasis added*).

Because these cases are before this Court on the basis of federal question jurisdiction and Fed. R. Bankr. P. 7004(d) provides for nationwide service of process, “the constitutional limits of the court’s personal jurisdiction are fixed … not by the Fourteenth Amendment but by the Due Process Clause but by the Due Process Clause of the Fifth Amendment.” *United Elec., Radio & Mach. Workers v. 163 Pleasant St. Corp.*, 960 F.2d 1080, 1085 (1st Cir. 1992); *see also Republic of Panama v. BCCI Holdings (Luxembourg) S.A.*, 119 F.3d 935, 942 (11th Cir. 1997) (“It is well

established that when ... a federal statute provides the basis for jurisdiction, the constitutional limits of due process derive from the Fifth, rather than the Fourteenth, Amendment.”).

Under the Fifth Amendment, “a plaintiff need only show that the defendant has adequate contacts *with the United States as a whole*, rather than with a particular state.” *United States v. Swiss Am. Bank, Ltd.*, 274 F.3d 610, 618 (1st Cir. 2001)(emphasis added); *see also In re Federal Fountain, Inc.*, 165 F.3d 600, 602 (8th Cir. 1999)(“the fairness that due process of law requires relates to ‘the fairness of the exercise of power by a particular sovereign ... and there can be no question ... that the defendant ... has sufficient contacts with the United States to support the fairness of the exercise of jurisdiction over him by a United States court.’”) (*quoting Fitzsimmons v. Barton*, 589 F.2d 330, 333 (7th Cir. 1979)); *Med. Mut. of Ohio v. deSoto*, 245 F.3d 561, 567-78 (6th Cir. 2001)(“[W]hen a federal court exercises jurisdiction pursuant to a national service of process provision, it is exercising jurisdiction for the territory of the United States and the individual liberty concern is whether the individual over which the court is exercising jurisdiction has sufficient minimum contacts with the United States.”); *Pinker v. Roche Holdings Ltd.*, 292 F.3d 361, 369 (3rd Cir. 2002)(holding that “a federal court’s personal jurisdiction may be assessed on the basis of the defendant’s national contacts when the plaintiff’s claim rests on a federal statute authorizing nationwide service of process.”).

Unlike as in diversity cases, the APAC Defendants’ contacts with the state in which the district court sits are irrelevant in federal question cases; what matters is their contacts with the United States. See, e.g., *Diamond Mortg. Corp. of Ill. v. Sugar*, 913 F.2d 1233, 1244 (7th Cir. 1990) (“Since section 1334 provides federal question jurisdiction, the sovereign exercising its authority over the [defendants] is the United States, not the State of Illinois. Hence, whether there exist sufficient minimum contacts between the [defendants] and the State of Illinois has no

bearing upon whether the United States may exercise its power over the attorneys pursuant to its federal question jurisdiction.”); *In re Celotex Corp.*, 124 F.3d 619, 630 (4th Cir. 1997) (“[W]hen an action is in federal court on ‘related to’ jurisdiction, the sovereign exercising authority is the United States, not the individual state where the federal court is sitting.”). This Court is quite familiar with this principle. See *Wang v. Schroeder*, C.A. No. 11-10009-RWZ, 2011 WL 6148579, * 4 (D. Mass. Dec. 9, 2011, Hon. R. Zobel)(“In federal question cases, the Due Process Clause of the Fifth Amendment (not the Fourteenth Amendment) requires only that defendants have minimum contacts with the United States as a whole rather than with a particular state.”).

There is no question that the APAC Defendants, doing business in Illinois and purchasing from a Massachusetts company, have adequate contacts with the United States. Therefore, this Court has personal jurisdiction over the APAC Defendants. Moreover, Plaintiffs have filed actions in federal court in Illinois that have been transferred to the MDL under 28 U.S.C. § 1407.¹⁰ The APAC Defendants cannot dispute that the Illinois transferor court has personal jurisdiction, and therefore, pursuant to transfer under Section 1407, this transferee Court exercises the same personal jurisdiction that the transferor court had over the APAC Defendants. See *In re Agent Orange Prod. Liab. Litig. MDL No. 381*, 818 F.2d 145, 163 (2d Cir. 1987)(“Transfers under Section 1407 are simply not encumbered by considerations of in personam jurisdiction and venue.... Following a transfer, the transferee judge has all the jurisdiction and powers over pretrial proceedings in the actions transferred to him that the transferor judge would have had in the absence of transfer.”); *In re Auto. Refinishing Paint Antitrust Litig.*, 358 F.3d 288, 297 n. 11 (3d Cir. 2004)(“the transferee court can exercise personal jurisdiction to the same extent that the transferor court could”); *In re WellNx Mktg. &*

¹⁰ Plaintiffs are in the process of working on motions to consolidate the actions transferred from Illinois with the actions filed in Massachusetts as part of the MDL.

Sales Practices Litig., 07-MD-1861, 2010 WL 3652457 (D. Mass. Sept. 15, 2010)(“In an MDL case, personal jurisdiction is derived from the transferor court.”); *In re Electronics Pacing Sys., Inc.*, 953 F. Supp. 909, 913 (S.D. Ohio 1997)(“In the context of cases consolidated for pretrial purposes under 28 U.S.C. § 1407, the court can exercise personal jurisdiction to the same extent as the transferor court could.”).

Plaintiffs have clearly established that this Court has personal jurisdiction over the APAC Defendants, therefore their motion to dismiss brought under F.R.C.P. Rule 12(b)(2) should be denied.

II. Plaintiffs Reserve the Right to Argue that Massachusetts Law Rather than Illinois Law Should Be Applied to the Instant Case

Plaintiffs do not concede that Illinois substantive law is applicable in the instant case, and importantly, the APAC Defendants fail to make any choice of law analysis whatsoever to support their contention that Illinois law applies to Plaintiffs’ claims.¹¹ In raising this issue, Plaintiffs reserve the right to fully brief the choice of law analysis at a later date. In sum, Plaintiffs will argue that the Commonwealth of Massachusetts has a significant interest in the litigation so as to make the application of Massachusetts substantive law appropriate. Plaintiffs contend that Massachusetts has a more significant interest than Illinois because the majority of the wrongful conduct, at the heart of this litigation, took place in Massachusetts. For example: the compounding facility at the source of this litigation was located in Massachusetts, the methylprednisolone acetate was actually compounded in Massachusetts, the contamination took place in Massachusetts, the APAC Defendants intentionally placed bulk orders to the facility they knew was regulated by the laws of Massachusetts not the FDA, the APAC Defendants had

¹¹ In their Motion to Dismiss, the APAC Defendants present no support for their contention that Illinois substantive law will be applicable, rather than Massachusetts substantive law.

the drugs shipped from Massachusetts, the APAC Defendants paid for the contaminated MPA and payment was processed in Massachusetts and the APAC Defendants did nothing to verify or investigate the safety measures taken by the facility. Consequently, since the majority of the wrongful conduct took place in Massachusetts, this court should apply Massachusetts substantive law to the instant case.¹² Nonetheless, Plaintiffs' complaints meet the pleading requirements of both Massachusetts and Illinois law and Plaintiffs address Illinois law herein in response to the APAC Defendants' motion.

III. Plaintiffs Sufficiently Allege a Claim for Negligence

A. Plaintiffs Pled Sufficient Allegations of Duty

The APAC Defendants cannot claim that Plaintiffs have failed to adequately plead that they owed a duty of reasonable care to the Plaintiffs, as there are several allegations related to duty set forth in the complaints. *See Master Compl., ¶¶ 152, 227-231.* It is well established that a physician's duty arises once a physician-patient relationship exists. *Reynolds v. Decatur Mem'l Hosp.*, 277 Ill. App. 3d 80, 85 (1996). It is indisputable that a physician-patient relationship existed between the Plaintiffs and Dr. Chang. Likewise, APAC owed the Plaintiffs a duty of reasonable care. Indeed, "Illinois has recognized that hospitals may be held liable for

¹² *Boston Hides & Furs, Ltd. v. Sumitomo Bank, Ltd.*, 870 F. Supp. 1153, 1166-67 (D. Mass. 1994) (In analyzing a choice of law issue, "[Massachusetts] courts preferred either a "place of conduct" analysis, focusing on the location of the alleged conduct which violated Chapter 93A (internal citation omitted) or a "functional approach" which "responds to the statutory concern with commercial conduct in Massachusetts."); *Auto Europe, LLC v. Connecticut Indem. Co.*, 321 F.3d 60, 66 (1st Cir. 2003) (Illinois plaintiffs filed a consumer fraud suit against an automobile insurance company and that company's insurer refused to defend it in the pending suit. The court held that even though plaintiffs were located in Illinois and the insurer was located in Florida, Maine law was applicable because the insured was located in Maine and the underlying lawsuit was based on wrongful conduct allegedly committed in Maine.); *Tingley Sys., Inc. v. CSC Consulting, Inc.*, 152 F. Supp. 2d 95, 115 (D. Mass. 2001) (In a misappropriation of trade secret claim, the court found the place of injury did not play an important role and, "[i]nstead, the principal location of the defendant's conduct is the contact that will usually be given the greatest weight in determining the state whose local law determines the rights and liabilities that arise from...the misappropriation of trade values." *Id.* quoting *Restatement (Second) of Conflict of Laws*, § 145, Comment (f) (1971).); See also *Data Cash Systems, Inc. v. JS & A Group, Inc.*, 480 F.Supp. 1063, 1071 (N.D.Ill.1979), *aff'd*, 628 F.2d 1038 (7th Cir.1980) ("...principal location of the defendant's conduct is the contact that is usually given the greatest weight in determining" the choice of law in an unfair competition claim).

institutional negligence,” as the courts have “acknowledged an independent duty of hospitals to assume responsibility for the care of their patients.” *Jones v. Chicago HMO Ltd. of Illinois*, 191 Ill. 2d 278, 291-92 (2000) (*citing Darling v. Charleston Community Memorial Hospital*, 33 Ill.2d 326, 211 N.E.2d 253 (1965)).

Both Dr. Chang and APAC are charged with, at minimum the duty to act “reasonably” and Plaintiffs have adequately alleged that such a duty exists in their complaints, which incorporate the Master Complaint. *Id.* (“a hospital must act as would a “reasonably careful hospital” under the circumstances.”); *see also Advincula v. United Blood Servs.*, 176 Ill. 2d 1, 22-24 (1996) (medical professionals “are held to a particularized form of the basic reasonable person standard because in addition to that degree of care, they are expected to possess a higher degree of skill, care, and learning than the average person.”)(*citing Purtill v. Hess*, 111 Ill.2d 229, 241–42 (1986)); *see also* Master Compl., ¶¶ 152, 227-231.

While the APAC Defendants do not appear to dispute that they owed the Plaintiffs a duty or that duty was sufficiently pled, they complain about Plaintiffs allegations related to the American Society of Health-System Pharmacy Guidelines on Outsourcing Sterile Compounding Services (“ASHP Guidelines”).¹³ It is well-established that when it comes to the APAC Defendants’ liability, “the standard of care … may be shown by a wide variety of evidence, including, but not limited to, expert testimony, hospital bylaws, statutes, accreditation standards, custom and community practice.” *Longnecker v. Loyola Univ. Med. Ctr.*, 383 Ill. App. 3d 874, 885 (2008) (*citing Jones*, 191 Ill.2d at 298, 246 Ill.Dec. 654, 730 N.E.2d 1119)). Moreover, despite the APAC Defendants’ allegations, guidelines may be used to establish the standard of

¹³ It is hard to tell whether the APAC Defendants really take issue with phraseology, particularly the use of the words “due diligence,” but if that it is the case, they have failed to establish how “due diligence” is any different from their duty to act with “reasonable care.” Semantics games should not be engaged by the Court. Moreover, Plaintiffs’ allegations related to the APAC Defendants duty set forth claims beyond just the allegations of “due diligence” owed to the Plaintiff, but those seem to be entirely ignored by the APAC Defendants.

care or considered as evidence of the standard of care. *See Matthews v. Aganad*, 394 Ill. App. 3d 591, 598-99 (2009) (“the evidence established that the standard of care was comprised of the CDC guidelines and physician judgment”). Defendants again cite to cases that are inapposite, involving internal rules of the transit authority, and not independent pharmacy guidelines, the inapplicability of high school level standards on elementary school level track meets, and the elements that establish the existence of a duty a hospital and a non-patient third-party.

It is clear that the APAC Defendants owed the Plaintiffs a duty to exercise reasonable care, and that failure to follow the ASHP Guidelines, is at the very least, evidence that they breached their duty. Moreover, it is well-established that the allegations set forth by Plaintiffs which allege that the exercise of due care requires compliance with the ASHP Guidelines are to be taken in the light most favorable to Plaintiffs. *See* Master Compl., ¶¶ 191-193, 234(e), 249, 255(b). Furthermore, Plaintiffs’ experts, at a more appropriate, less premature time, will testify similarly. Because the Plaintiffs have sufficiently set forth allegations sufficient to establish plausible entitlement to relief, the APAC Defendants’ motion should be denied.

B. Plaintiffs Pled Sufficient Allegations of Causation

The Plaintiffs have sufficiently set forth causation allegations establishing plausible entitlement to relief. In making their unsubstantiated arguments, the APAC Defendants completely ignore over thirteen pages in the Master Complaint that allege numerous negligent acts and omissions by the APAC Defendants and that those acts caused Plaintiffs to be injected with contaminated drugs from NECC that resulted in their injuries. *See* Master Compl., ¶¶ 151-206, 226-242. Consequently, when viewing more than just the one selective allegation referenced by the APAC Defendants, it is evident that Plaintiffs have sufficiently plead allegations to suggest both factual and proximate causation. Master Compl., ¶¶ 153, 174, 189,

199, 205-206, 207-210, 236- 242.

Plaintiffs' allege that multiple wrongful acts of the APAC Defendants caused their injuries. Indeed, the Plaintiffs allege that the APAC Defendants were negligent in purchasing non-FDA approved preservative-free drugs, to be injected directly into Plaintiffs' vulnerable central nervous systems, from an unaccredited compounding facility, in bulk and under false names, and failing to perform any due diligence on NECC before purchasing and administering its products into Plaintiffs. *See Master Compl.* ¶¶ 154-155, 158-163, 165-166, 174-176, 180, 192, 199, 204, 234(a)-(q). Furthermore, Plaintiffs have alleged that but for the APAC Defendants' negligent acts and omissions, Plaintiffs would not have been injected by the APAC Defendants with contaminated drugs resulting in injuries. *See Master Compl.*, ¶¶ 153, 174, 189, 199, 205-206, 207-210, 237-242. After all, the APAC Defendants were the last party to touch the NECC contaminated product and the party responsible for actually injecting it into the Plaintiffs. Had they acted non-negligently, Plaintiffs never would have received the contaminated injections from NECC.

Additionally, contrary to what the APAC Defendants would like the Court to believe, courts in Illinois have held that concurrent or multiple causes can serve as the proximate cause for an injury and illness to a plaintiff. *See Nolan v. Weil-McLain*, 233 Ill. 2d 416, 437 (2009) (“The concurrent negligence of others does not relieve a negligent defendant from liability.”)(citing *Lipke v. Celotex Corp.*, 153 Ill. App. 3d 498, 509 (1987)). Indeed, it is well established that there “can be more than one proximate cause of an injury...[i]n such a situation, one guilty of negligence cannot avoid responsibility merely because another person is guilty of negligence contributing to the same injury, even though the injury would not have occurred but for the negligence of the other person.” *Sears v. Kois Bros. Equipment, Inc.*, 110 Ill. App. 3d

884, 888 (1982). Therefore, the fact that NECC may also have been negligent and contributed to the Plaintiffs injuries, as alleged by the APAC Defendants, does not relieve them from liability for their own negligence that also contributed to the Plaintiffs injuries.

Lastly, “proximate cause of an injury is ordinarily a question of fact, to be determined by the jury from a consideration of all attending circumstances.” *Sabo v. T.W. Moore Feed & Grain Co.*, 97 Ill. App. 2d 7, 15 (1968), *citing* *Phillabaum v. Lake Erie & W. R. Co.*, 315 Ill 131, 135 (1924). Plaintiffs have sufficiently set forth allegations of causation, warranting denial of Defendants’ motion to dismiss.

IV. Plaintiffs Set Forth Sufficient Allegations to State a Claim for Violations of Illinois’ Consumer Fraud and Deceptive Business Practices Act

Because Plaintiffs have adequately pled their claims pursuant to the Illinois Consumer Fraud and Deceptive Business Practices Act (the “Act”), the APAC Defendants have resorted to misconstruing case law and reaching false conclusions regarding Plaintiffs’ allegations in their attempt to dismiss Plaintiffs’ claims under the Act. However, the case that the APAC Defendants allege is so similar to the instant case is in fact drastically different. In *Walton*, the court found that the plaintiff had not sufficiently pled a claim under the Act because the complaint only asserted general allegations dealing with the development, production, labeling, and marketing of Yasmin, which clearly did not implicate the defendant pharmacy that simply filled the Yasmin prescription. *Walton v. Bayer Corp. (In re Yasmin & Yaz (Drospirenone) Mktg., Sales Practices & Prods. Liab. Litig.)*, 692 F. Supp. 2d 1012, 1023-24 (S.D. Ill. 2010). Clearly, the actions of a pharmacy filling a prescription order are in no way the same as the APAC Defendants’ conduct alleged by Plaintiffs and discussed below.

Ignoring the majority of Plaintiffs’ allegations in the Master Complaint, the APAC Defendants erroneously assert that generating fraudulent billing records is the sole basis of

Plaintiffs' claims of violation under the Act. APAC MTD, pg. 17. Violations of the Act include the use of any deception, fraud, false pretense, false promise, *misrepresentation, or concealment of facts* in the conduct of trade or commerce. 815 ILCS 505/2 (*emphasis added*). Plaintiffs have alleged such violations, including that the APAC Defendants "deceptively concealed" vital information about the product and made various misrepresentations about the standard, quality, grade, uses and benefits of the contaminated MPA, such as representing to their patients, including Plaintiffs, that they "were receiving FDA-approved Depo-medrol when in fact they injected patients...with NECC's compounded MPA." Master Compl., ¶¶ 243, 247, 251, 253. The misrepresentations on the billing records that the APAC Defendants solely focus on are just one example of the APAC Defendants' deceptive acts and practices alleged by Plaintiffs.

Plaintiffs have sufficiently alleged violations of the Act plausible to entitle them to relief. See Master Compl., Count IV. Moreover, all the APAC Defendants may be held liable under M.G.L. c. 93A. See M.G.L. c. 93A, §§ 1, 9. For these reasons, Plaintiffs request this Court deny the APAC Defendants' motion to dismiss their claims under the Illinois Consumer Fraud and Deceptive Business Practices Act.

V. Illinois Product Liability Law

A. Plaintiffs' Properly Allege Violation of Illinois Products Liability Law.

Plaintiffs sufficiently pled allegations in the Master Complaint to suggest the validity of their claims of violation of the Illinois Products Liability Law that were explicitly identified in Plaintiffs' Short Form Complaints. Plaintiffs adopted and incorporated all facts and allegations set forth in the Master Complaint into their Short Form Complaints. See Musselwhite Amended Short Form Compl., Dkt. No. 1:13-cv-13228-RWZ, Doc. No. 6, ¶ 1; see also Kennedy Amended Short Form Compl., Dkt. No. 1:13-cv-13227-RWZ, Doc. No. 6, ¶ 1. Defendants intentionally

disregard all the allegations made against them in the Master Complaint, even if they were not specifically directed at Illinois Products Liability Law. Master Compl. ¶¶ 151-210. The APAC Defendants also fail to cite any case law to support their contention that Plaintiffs must explicitly reference the Illinois statute.

In seeking dismissal of Plaintiffs' Illinois Products Liability Law claims, Defendants completely ignore the usual MDL process and the fact that the Master Complaint specifically states “[t]his master complaint is filed for administrative purposes only” and was drafted pursuant to MDL Order No. 6. Master Compl. ¶ 9. As such, the Master Complaint is no more than an administrative or procedural device. *See In re Propulsid Products Liability Litigation*, 208 F.R.D. 133, 142 (E.D. La. 2002); *In re Vioxx Products Liability Litigation*, 239 F.R.D. 450, 454 (E.D. La. 2006) (noting that a master complaint is simply “an administrative device used to aid efficiency and economy and, thus, should not be given the status of an ordinary complaint.”); *In re Mercedes-Benz Tele Aid Contract Litig.*, 257 F.R.D. 45, 56 (D.N.J. 2009) (“In the absence of ...consent, the majority of courts treat consolidated complaints filed in multi-district litigations as a procedural device rather than a substantive.”); *Guidant Corp. Implantable Defibrillators Products Liability Litigation*, 489 F.Supp.2d 932, 936 (D.C. Minn. 2007) (“Consolidation of a master complaint is merely a procedural device designed to promote judicial economy, and, as such, it does not affect the rights of the parties in separate suits.”).

In the normal course, master complaints are adopted by short form complaints, and further long form complaints are drafted and filed when a cases is selected for a bellwether trial. This is the efficient way of moving cases forward in a MDL involving the laws of dozens of states, and in fact, the number of motions to dismiss filed in the MDL at this stage is unprecedented. The Master Complaint sets forth allegations across fifty states; certainly it would

have been inconsistent with legal parameters of an administrative complaint, been unduly burdensome and unworkable for Plaintiffs to break down the status of products liability law in every state under consideration.

Nonetheless, even if the Court were to agree with Defendants that the Master Complaint Count needs to specifically identify Illinois Products Liability Law, dismissal is not the appropriate remedy. Plaintiffs should have an opportunity to amend the Master Complaint to specifically name the Illinois Products Liability Law. *See Taylor v. Trans Acceptance Corp.*, 267 Ill. App.3d 562, 573 (1994) (Plaintiffs generally should be granted at least one chance to amend their pleadings before court dismisses a complaint with prejudice); *see also Gouge v. Central Illinois Public Service* (1990), 195 Ill.App.3d 1026, 1032, 552 N.E.2d 1304, 142 Ill. Dec. 563, rev'd on other grounds *Gouge v. Central Illinois Public Service* (1991), 144 Ill.2d 535, 582 N.E.2d 108, 163 Ill. Dec. 842 (“A cause of action should be dismissed with prejudice on the pleadings only if it clearly appears that no set of facts can be proved which will entitle the plaintiffs to recover, and then only if it is apparent that even after amendment, if leave to amend is sought, no cause of action can be stated.”). Therefore, Defendants’ motion should be denied.

B. The Sale of Contaminated MPA is Subject to Strict Liability Pursuant to Illinois Products Liability Case Law.

The APAC Defendants’ sale of contaminated MPA falls squarely within the purview of Illinois strict product liability law. Under Illinois product liability law, “[o]ne who sells any product in a defective condition unreasonably dangerous to the user or consumer...is subject to liability for physical harm thereby caused to the ultimate user or consumer...if the seller is engaged in the business of selling such a product, and it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold.” *Glassman v. Wyeth Lab. Inc.*, 238 Ill. App. 3d 533, 537 (1992).

According to itemized billing statements, the APAC Defendants charged Plaintiffs \$60 for “Depo-Medrol 80 mg (J1040)” plus \$1,500 for the actual medical service of the injection itself for each epidural steroid injection Plaintiffs received. *See Exhibit B.* Thus, the APAC Defendants were sellers of the contaminated MPA that they administered to their patients, including Plaintiffs. Additionally, the courts in Illinois have held that even “the *dispensation* of drugs and other medications by hospitals or other entities, where injury or disease resulting from the existence of deleterious contaminants therein would most assuredly result in the application of the strict liability theory.” *Cunningham v. MacNeal Memorial Hosp.*, 47 Ill. 2d 443, 453 (1970) (emphasis added) (narrowly superseded by statute).¹⁴ In the present case, the APAC Defendants sold and dispensed contaminated MPA to Plaintiffs that resulted in catastrophic injuries.

Cases relied upon by the APAC Defendants are entirely inapposite. Indeed, the APAC Defendants rely upon the *Stiffler* case involving a prosthesis in an attempt to establish that product liability law does not apply to medical procedures. *Stiffler v. Lutheran Hosp.*, 965 F.2d 137, 141 (7th Cir. 1992). Unlike the case here, the court held that the hospital “was in no better position than Stiffler to examine the product and discover the defect.” *See id.* This is patently untrue in the case at hand, as set forth in the Master Complaint’s allegations regarding the clinic’s decision to forgo performing any diligence whatsoever on NECC, its compounding process, facility, drugs, etc., before injecting Plaintiffs (who unlike Stiffler, cannot see the MPA) with contaminated steroids in the their spines. The APAC Defendants also incorrectly analogize the circumstances of this case with the facts of *Greenberg v. Michael Reese Hospital*, 83 Ill.2d 282, 291 (1980). In *Greenberg*, the court stated that a claim for strict product liability must

¹⁴ The Blood and Organ Transaction Liability Act (Ill. Rev. Stat. 1983, ch. 111 ½, par. 5102), overruled the applicability of *Cunningham* “only as to human blood products and tissue.” *Brandt v. Boston Scientific Corp.*, 204 Ill.2d 640, 650 (2003).

allege the presence of a deleterious contaminant, not that product liability is inapplicable for products administered during medical services. *Id.* at 288-89. In the present case, Plaintiffs allege the existence of deleterious contaminants in the MPA that was sold and administered to them. As the seller and dispenser of the dangerously contaminated MPA, the APAC Defendants are liable under Illinois products liability law. Plaintiffs have sufficiently pled allegation setting forth a plausible entitlement to relief. Therefore, the APAC Defendants' motion should be denied.

VI. Plaintiffs Sufficiently Set Forth a Failure to Warn Claim

The APAC Defendants' assertion that Plaintiffs do not allege that the Clinic Related Defendants knew or should have known "that the use of preservative-free MPA or a compounded drug, generally, presents a high-risk to patients or is unreasonably dangerous[]” is patently false. APAC MTD, pg. 20-21. Plaintiffs set forth numerous factual allegations in the Master Complaint regarding what the APAC Defendants knew or should have known, in part, 1) about the risks and dangers associated with the use of non-FDA approved compounded drugs due in large part to the fact that compounding pharmacies are not required to meet the stringent FDA-regulated manufacturer quality controls and measures, and 2) the risks and dangers associated with the procedure of injecting immune system suppressing preservative-free (leaving it open to contamination without the preservative) MPA directly into the vulnerable central nervous system (where the bodies normal antibodies to fight infection are not present. See Master Compl. ¶¶ 48-55, 151-206.

Ignoring all the allegations made by Plaintiffs concerning what the APAC Defendants

knew or should have known regarding the risks associated with compounded drugs¹⁵, particularly preservative-free MPA, the APAC Defendants make the unsubstantiated argument that Plaintiffs do not allege unequal knowledge with respect to the risk of harm and then attempt to shift the duty and subsequent failure to warn onto NECC as the “manufacturer.” APAC MTD, pg. 21; *see* Master Compl. ¶¶ 48-55, 151-206. This flawed argument disregards well-established Illinois law, setting forth that where there is a physician-patient relationship, “consumers should principally look to their prescribing physician to convey the appropriate warnings regarding drugs, and it is the prescribing physician’s duty to convey these warnings to the patients.” *Frye v. Medicare-Glaser Corp.*, 153 Ill. 2d 26, 34-35 (1992). The APAC Defendants breached this legal duty to Plaintiffs by failing to convey appropriate warnings regarding the compounded preservative-free MPA and the risks associated with the procedure, the compounded drug and the availability of a safer alternative. As Plaintiffs allege in their Complaint, had they been informed of the true nature of the drugs they were receiving, they would have declined treatment with NECC drugs. See Master Compl., ¶ 302. Therefore, Plaintiffs have sufficiently pled a failure to warn claim under Illinois law and this count should not be dismissed.

VII. Plaintiffs Have Sufficiently Pled a Cause of Action for Agency Under Illinois Law

The existence of an agency relationship is a question of fact to be decided by the trier of fact, unless the parties’ relationship is so clear as to be undisputed. *Pomper & Goodman v. Stang*, 2011 Ill. App. Unpub. Lexis 2030. In Illinois, the party claiming an agency relationship does not need to include sufficient facts in its complaint to enable the trial court to resolve the

¹⁵ Even assuming the APAC Defendants, a pain management company spanning two states with eighteen different locations and a board certified physician in Pain Management and Anesthesiology, were somehow not aware of the risks associated with compounding pharmacies, they became well informed on March 23, 2012 when a Pharmaceutical Compounding Accrediting Board (“PCAB”) certified compounding pharmacy representative sent multiple documents highlighting the dangers related to compounded medication. *See Exhibit C.*

agency issue. *Sherman v. Field Clinic*, 74 Ill. App. 3d 21, 25-26, 392 N.E.2d 154, 158 (1979); see *Prof'l Group Travel, LTD. v. Prof'l Seminar Consultants, Inc.*, 136 Ill. App. 3d 1084, 1091, N.E.2d 1291, 1296 (1985). The allegation that a tortious act was done on the alleged principal's behalf is sufficient to withstand a motion to dismiss a claim of agency. *Id.* The principal consideration in determining whether an agency relationship exists is the principal's right to control the manner that the work is done by the agent. *Chemtool, Inc. v. Lubrication Techs.*, 148 F.3d 742, 745 (7th Cir. Ill. 1998).

Plaintiffs have alleged sufficient facts which, if proved, establish the existence of an agency relationship. *Connick v. Suzuki Motor Co.*, 174 Ill. 2d 482, 497, 675 N.E.2d 584 (Ill. 1996) ("A complaint relying on agency must plead facts which, if proved, could establish the existence of an agency relationship"). The complaints allege that NECC committed a "tortious act" by negligently compounding pharmaceuticals, which were compounded on behalf of and at the direction of the APAC Defendants. *Sherman*, 74 Ill. App. 3d at 25-26; *Prof'l Group Travel, LTD.*, 136 Ill. App. 3d at 1091; see also Master Compl., ¶ 332, 334. Furthermore, Plaintiffs have alleged that NECC did in fact compound, sell and deliver drugs to the APAC Defendants, thereby consenting to act as the APAC Defendants' agent. See Master Compl., ¶ 333. When viewed in a light most favorable to Plaintiffs, the foregoing alleged facts adequately suggest the existence of an agency relationship sufficient to survive a Rule 12(b)(6) motion. Therefore, the agency claims against the APAC Defendants should not be dismissed.¹⁶

¹⁶ In the alternative, should this Court find that Plaintiffs have not met their burden in alleging an agency cause of action, Plaintiffs should be provided the right to amend the claim to one of independent contractor vicarious liability pursuant to Restatement (Second) of Torts § 414, imposing liability when the authority to stop the work for safety reasons is retained.

VIII. Plaintiffs Have Sufficiently Pled a Claim for Civil Conspiracy Under Illinois Law

In their Motion to Dismiss, the APAC Defendants contend¹⁷ that even assuming they provided NECC with “bogus patient lists” to purchase MPA in bulk in violation of Massachusetts Board of Pharmacy (the “Board”) rules and regulations, Plaintiffs have not pled a cause of action for civil conspiracy because “[t]hese patient lists are not alleged to have caused the contamination[]” and “these lists or the agreement related to these lists was not entered into ... knowing that it could have or would have led to the contamination of MPA or the injury at issue.” APAC MTD, 23-24. Without providing a single case in support of their argument, the APAC Defendants would have this Court erroneously believe direct causation and specific knowledge of the overt tortious or unlawful act are elements of civil conspiracy under Illinois law. This simply is not true.

Illinois law defines civil conspiracy as: “(1) a combination of two or more persons, (2) for the purpose of accomplishing by some concerted action either an unlawful purpose or a lawful purpose by unlawful means, (3) in the furtherance of which one of the conspirators committed an overt tortious or unlawful act.” *Foodcomm Int’l v. Barry*, 463 F. Supp. 2d 818, 830 (N.D. Ill. 2006) quoting *Fritz v. Johnston*, 807 N.E.2d 461, 470 (Ill. 2004). Thus, Plaintiffs sufficiently pled all the elements of civil conspiracy by alleging that the unlawful concerted actions by the APAC Defendants and NECC allowed NECC to falsely maintain compliance with the Board to further violate the rules and regulations meant to ensure patient health and safety. *See* Master Compl., ¶¶ 337-51. Additionally, Illinois finds that “a defendant who understands the general objectives of the conspiratorial scheme, accepts them, and agrees, either explicitly or

¹⁷ The APAC Defendants state that Rule 9(b) applies to civil conspiracy claims premised on alleged fraud but fail to argue how the heightened pleading requirements have not been met. Plaintiffs contend that sufficient facts have been alleged to satisfy even the stringent pleading standards under Rule 9(b) for civil conspiracy.

implicitly to do its part to further those objectives...is liable as a conspirator." *Id.* (*quoting Adcock v. Brakegate, Ltd.*, 164 Ill. 2d 54, 64 (Ill. 1994)). Plaintiffs have set forth a sufficient claim of civil conspiracy under Illinois law, and thusly the APAC Defendants' Motion to Dismiss this claim should be denied.

IX. Plaintiffs' Allegations are Sufficient to Support an Award of Punitive Damages under Illinois Law

Plaintiffs' allegations sufficiently state a claim for punitive damages. "It has long been established in [Illinois] that punitive or exemplary damages may be awarded when torts are committed with fraud, actual malice, deliberate violence or oppression, or when the defendant acts willfully, or with such gross negligence as to indicate a wanton disregard of the rights of others." *Rockford Redi-Mix, Inc. v. Teamsters Local 325*, 195 Ill. App.3d 294, 309 (1990)(citing *Kelsay v. Motorola, Inc.*, 74 Ill.2d 172, 186 (1978)). In the Master Complaint, Plaintiffs allege that the APAC Defendants acted willfully or with such gross negligence as to indicate a wanton disregard of the rights of others, specifically that:

238. The actions of the Clinic Related Defendants did not meet even the most minimal diligence to ensure that they were not injecting contaminated, adulterated, tainted, and unreasonably dangerous drugs directly into the bodies of their patients, including Plaintiffs.

239. The acts and omissions of the Clinic Related Defendants constituted such ***utter disregard for the rights of others***, and such utter disregard for prudence, that they amount to complete neglect of the safety of patients, including Plaintiffs.

240. The acts and omissions of the Clinic Related Defendants were a heedless and palpable violation of their legal duties respecting the life and rights of Plaintiffs and constitute ***gross negligence***.

241. Plaintiff's injuries, distress, and/or death occurred as a proximate result of the ***grossly negligent acts*** and omissions of the Clinic Related Defendants.

* * *

249. Clinic Related Defendants *willfully and knowingly* failed to abide by regulations, laws and guidelines set forth to protect consumer safety, constituting a violation of the consumer protection statutes set forth herein.

250. Clinic Related Defendants' *willful and knowing* withholding of important safety information and critical product information constitutes a violation of various state consumer protection statutes set forth herein.

251. Clinic Related Defendants *actively, knowingly, and deceptively* concealed the product's dangerous properties and life-threatening risks of which they knew or should have known [sic]. This conduct evidences bad faith and unfair and deceptive practices.

See Master Compl., ¶¶ 238-251.

Because Plaintiffs have alleged that the APAC Defendants acted either "willfully or with such gross negligence as to indicate a wanton disregard for others," Plaintiffs have adequately and sufficiently established a plausible entitlement to relief under Illinois punitive damages law. Furthermore, dismissal on this Count would be premature, as Plaintiffs have not had the benefit of discovery to fully develop their claim for punitive damages, and it is well known that defendants do not make their reckless conduct publically known. The Court should deny the APAC Defendants motion to dismiss and allow discovery on these issues.

CONCLUSION

For the foregoing reasons, Plaintiffs respectfully request that this Court deny the APAC Defendants' Motion to Dismiss in its entirety. In the alternative, should this Court determine that Plaintiffs' allegations are deficient, Plaintiffs respectfully request the opportunity to amend their complaints to provide further allegations.

Date: September 26, 2014

Respectfully Submitted,

/s/ Kimberly A. Dougherty

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CERTIFICATE OF SERVICE

I, Kimberly A. Dougherty, hereby certify that I caused a copy of the above to be filed electronically via the Court's electronic filing system. Those attorneys who are registered with the Court's electronic filing system may access these filings through the Court's system, and notice of these filings will be sent to these parties by operation of the Court's electronic filing system.

Dated: September 26, 2014

/s/ Kimberly A. Dougherty
Kimberly A. Dougherty, Esq.